PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Van Dyke, et al.	Group Art Unit: 1651
Serial No.: 09/899,372	Examiner: Isis A.D. Ghali
Filed: July 2, 2001	Atty. Dkt. No.: KER020/4-005CON
For: SOLUBLE KERATIN PEPTIDE	Confirmation No. 3035

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

The present notice of appeal and appeal brief in triplicate are filed in response to a Final Official Action of March 7, 2007. A Notice of Appeal and Petition for Extension of Time were filed on August 7, 2007, making the due date for this brief December 7, 2007. This brief is thus believed to be timely filed. The amount of $255.00 for filing a brief in support of appeal according to 37 CFR 41.20(b)(2) is being paid electronically. If the authorization is inadvertently omitted, or should any additional fees be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Vinson & Elkins L.L.P. Deposit Account No. 22-0365/KER020/4-005CON.

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BRIEF ON APPEAL

I. REAL PARTIES IN INTEREST

The real parties in interest are Mark E. Van Dyke, Cheryl R. Blanchard, Scott F. Timmons, Arlene J. Siller-Jackson, Robert A. Smith, Keraplast Technologies, Ltd., Keratec Limited, KMS Ventures, Inc., Crymes G. Pittman, and Robert E. Gray.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 55-65, 67, 68, and 93 are rejected. Claims 1-54 were canceled without prejudice and claims 55-96 were added in a Preliminary Amendment of July 2, 2001. Claim 66 was canceled without prejudice in a response to an Office Action of January 22, 2003. Claims 69-92 and 94-96 were withdrawn from consideration as drawn to non-elected species in response to an Office Action of April 25, 2005. Claims 55-65, 67, 68, and 93 are being appealed.

IV. STATUS OF AMENDMENTS

All amendments have been entered and considered by the Examiner.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The application at issue contains two independent claims: claims 55 and 93. Claim 55 is drawn to a composition comprising water soluble peptides, wherein the peptides are obtained by: oxidizing human or animal hair, human or animal nails, fur,

hooves, or feathers, in an aqueous oxidizing solution; filtering the aqueous oxidizing solution to obtain a water soluble portion; substantially neutralizing the water soluble portion; and adding a water-miscible organic solvent to the water soluble portion, such that a precipitate is formed; wherein the precipitate comprises water soluble peptides; and further wherein at least about 90% of said water soluble peptides are between about 300 and about 1300 Daltons in molecular weight.

In one method, hair is oxidized with a sufficient concentration of oxidizing agent for a sufficient time and temperature so as to cleave a significant portion of the hair disulfide bonds, such that some disulfide bonds are oxidized to form hydrophilic groups such as sulfonic acid and such that water-soluble peptides are produced. Examples of oxidizing agents include, but are not limited to, hydrogen peroxide, peracetic acid, percarbonates, persulfates, chlorine dioxide, sodium and calcium peroxides, perborates, and hypochlorite. Methods for oxidation are described in paragraph [0015]. The oxidized hair can be recovered, for example by filtration (Para. [0016]), the filtrate collected, and neutralized with base, for example ammonium hydroxide (Para. [0017]). Water soluble peptides from the neutralized filtrate can be precipitated from solution by mixing the filtrate with a water-miscible organic solvent such as methanol, ethanol, acetone, or tetrahydrofuran, as described in paragraph [0018]. The precipitate can be collected using centrifugation and the collected filtrate dried, as described in paragraph [0019]. In one method, about 20 percent of the original hair mass is collected as peptide material after drying. The dried precipitate can be ground into a fine powder.

Peptides produced according to the present invention are largely water soluble and have an average molecular weight of about 850 Daltons and an average chain length of about 10 amino acids. One product made according to the present invention is a powder that is whitish to yellow in color and readily soluble in water.

The second independent claim, claim 93, is drawn to a composition for a topical application for skin wherein the composition comprises the composition of claim 55 further comprising the step of drying the precipitate to a powder. Applications for the compositions described are detailed in paragraphs [0021] and [0022].

VI. GROUNDS OF REJECTION TO BE REVIEWED

1. Are claims 55-56, 67, and 68 sufficiently enabled under 35 U.S.C. § 112, first paragraph?

2. Are claims 55-65, 67, 68, and 93 unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,276,138 (Yamada)?

VII. ARGUMENT

1. The claims are enabled under 35 USC §112, first paragraph for a composition of water soluble peptides and there is no legal requirement that the Specification describe and/or enable every possible use for that composition.

The first paragraph of 35 U.S.C. § 112 requires the Specification to enable a person skilled in the art to make and use the claimed invention. The MPEP elaborates on use requirement as it provides, "if a statement of utility in the Specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied." MPEP § 2164.01(c). Further, "if any use is enabled when multiple uses are disclosed, the application is enabling for the invention." *Id.* Thus, when a claim is drawn to a composition, there is no legal requirement that the Specification describe or enable *every* possible use for that composition so long as at least one use is enabled.

A. The Examiner's enablement rejection misconstrues the invention and improperly reads a new limitation into it.

The Examiner's rejection of the claims for lack of enablement is based the erroneous concept that the claimed material must be used only in therapeutic formulations, and further only in topical therapeutic formulations. *See* Final Office Action dated March 7, 2007, page 3 ("[T]he specification has enabled how to make the peptide composition and how to use it topically to stimulate growth of useful cell types, and has not enabled any uses other than topically for stimulating wound healing and cell growth."). Although the Specification describes therapeutic formulations that may be made with the claimed composition, including topical formulations, the claimed composition is in no way limited to those described formulations. The invention of claim

55 is the powdered peptide composition. The composition is shown in the application to have useful bioactivity. *See* Para. [0021]-[0022]. The Examiner is attempting to read a limitation into the claims based on the described preferred embodiments. The Examiner's position is contrary to the MPEP's statement that "if *any* use is enabled when multiple uses are disclosed, the application is enabling for the invention." MPEP§ 2164.01(c) (emphasis added).

In fact, the Specification discloses many uses for the composition that are known in the art and would not require undue experimentation. The Specification fully enables one of skill in the art to manufacture and use the claimed composition in a formulation for topical administration via a cream, lotion, gel, hydrogel, or wound dressing to a human or animal subject. Para. [0021-0022]. That enablement alone is enough to satisfy the section 112, first paragraph, requirement. But the Specification goes further and provides more uses that are broader than topical application. It says, for example, "the peptide can be used to promote healing, repair, and cell growth in keratinous tissue generally." Para. [0021]. In contrast to the Examiner's assertion that the Specification does not disclose uses other than topical application, the Specification explicitly states that the peptide can be administered orally. Para. [0021] ("[T]he peptide can be applied internally to damaged keratinous tissue lining the GI tract by **orally administering the peptide**."). The composition could also be used as a nutritional supplement, for example. The Examiner is not only attempting to read a limitation into the claims, she is also imposing a requirement on the Specification that has no basis in the body of patent law. In sum, the application discloses multiple uses for the composition and is enabled as to at least one of those uses, therefore the invention is enabled and satisfies section 112. MPEP § 2164.01(c).

B. Additionally, the Examiner did not meet her burden to show that undue experimentation would be necessary.

The invention is fully enabled because at least one use, as a topical application, is enabled. But even if other uses must also be enabled, the Examiner did not meet her burden to show that undue experimentation would be necessary. "The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." MPEP 2164.01 (citing *In re Angstadt*, 537 F.2d 498, 504, 190

USPQ 214, 219 (CCPA 1976)). The Examiner claimed that the composition is not enabled as to non-topical applications because it would require undue experimentation. *See* Final Office Action dated March 7, 2007, page 4. Tellingly, the Examiner offered no explanation of what experimentation would be required, and why any such experimentation would be "undue," other than to say that trial and error experimentation would be required. *Id.* Clearly, the Examiner did not meet her "burden to establish a reasonable basis to question the enablement provided." MPEP 2164.04. Where no explanation is offered, there is simply no basis for a reasonable explanation.

C. Use as an orally administered peptide is enabled in the Specification because methods of use for orally administered peptides are well known in the art.

Even if experimentation would be required to enable an orally administered peptide, the MPEP provides that "[i]f one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 U.S.C. 112, first paragraph." MPEP § 2164.01(c); *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) ("A patent need not disclose what is well known in the art."). Methods of use for orally administered proteins are well known in the art. It is a well known fact that proteins and peptides are composed of amino acids, and that amino acids have nutritional value. Many protein and amino acid supplements are now commercially available. No or little experimentation is necessary to place the peptides in a gel capsule or compress them into a tablet, for example, to be used as an oral supplement for its known nutritional value. Neither would it require undue experimentation to determine whether such supplementation would have a healing effect on the lining of the gastro-intestinal tract. Thus, the Specification satisfies section 112, first paragraph, because placing proteins in an orally administered form is well known in the art. MPEP § 2164.01(c).

D. The Examiner's reliance on *In re Wands* is misplaced because the criteria in *Wands* are not applicable to the present composition claim.

The Examiner relied on the factual inquiries as applied in *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed Cir. 1988), to reach her conclusion that the claims are not enabled for the full scope of the claims. The criteria in *Wands* are not applicable to the present composition claim. For example, the question in *Wands* was whether the Specification taught one of skill how to make the antibodies that were used in the claimed method of immunoassay to detect hepatitis B surface antigen. *Wands*, 858 F.2d at 733. Nowhere do Appellants find an issue of whether all possible uses of the antibodies were enabled. In addition, in all the various later Federal Circuit cases that have cited *In re Wands*, Appellants cannot find a single one that applies the *Wand* factors to a composition claim to determine whether all possible uses of the composition are enabled by the Specification.

The issue here is not whether the Specification enables all possible uses of the compositions of peptides, but rather, the enablement of the peptide composition independent of adding it to a particular type of carrier. The Specification contains more than adequate description of how to obtain the peptide composition and also teaches how to use the composition to stimulate growth of useful cell types. Nothing more is required for enablement of the composition claims. Appellants submit, therefore, that this rejection is improper and requests that the rejection be overturned.

2. Claims 55-65, 67, 68, and 93 are not unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,276,138 (Yamada).

The prior art rejection is improper, at least because the Examiner has failed to fully consider the scope and content of the prior art or ascertain the differences between the prior art and the claims in issue, as required by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966) (reaffirmed in *KSR Int'l Co. v. Teleflex Inc.,* 82 USPQ 2d 1385, 1391 (2007)) and as cited in MPEP 2141, which states that these guidelines are to be applied in *each and every case*. Patentability is determined by:

A) Determining the scope and content of the prior art;

B) Ascertaining the differences between the prior art and the claims in issue;

C) Resolving the level of ordinary skill in the art; and

D) Evaluating objective evidence of non-obviousness.

A. The scope and content of the '138 reference do not in any way include or suggest all the elements of the present claims.

The Examiner rejected claims 55-65, 67, 68, and 93 as obvious over 5,276,138 ('138) because, according to the Examiner, the "'138 patent teaches a solubilized keratin powder from animal hair or wool" and teaches the steps "oxidation by hydrogen perioxide or peracetic acid; filtration, neutralization, precipitation of a powder; and washing the filtrate with solvent such as acetone, methanol or ethanol." Final Office Action dated March 7, 2007, page 6. Appellants respectfully traverse the rejection because the present invention is based on the surprising result that the *filtrate* of oxidized hair contains biologically active peptides that can be collected by neutralizing the filtrate and precipitating out the peptides with a water-miscible organic solvent. Para. [0009]. The '138 patent teaches discarding the *filtrate* of oxidized hair and using the *precipitate* to recover much larger molecular weight proteins. Col. 4, lines 29-33; Example 1 at Col. 5-6. Thus, the '138 patent contains no description or suggestion of the present invention.

B. The '138 reference describes a different process for obtaining the peptides.

'138 teaches a process by oxidizing the hair, filtering it through a mesh (discarding the filtrate), precipitating with an acetic acid, filtering through a filter paper (discarding the filtrate), washing, drying, and pulverizing to obtain a powder. *See e.g.,* ('138) Example 1 at Col. 5-6. The present disclosure, on the other hand, teaches a different process; oxidizing the hair, filtering it (retaining the filtrate to collect the low molecular weight, water-soluble peptides), neutralizing the filtrate with a base, precipitating out the water-soluble peptides by mixing with a water-miscible organic solvent, filtering again and evaporating the precipitate. Para. [0014]-[0018]. Thus, the '138 reference teaches one skilled in the art to discard the objects of the present composition claims by disposing of the filtrate in the first filtration step. The '138 process contains no description of the water-soluble peptides found in the filtrate of the oxidized hair. The present disclosure is not obvious in light of the '138 reference because that reference does not teach or describe the surprising result that the filtrate of oxidized

hair contains biologically useful peptides, which are the compositions claimed in the present disclosure.

C. The '138 reference describes different proteins.

The '138 patent describes a composition containing high molecular weight, acid precipitable proteins. This subset of hair proteins is an acidic portion of the oxidized hair that is insoluble at low pH, and thus precipitates in acid. This protein subset has a much higher molecular weight than the peptides precipitated by ethanol at neutral pH as described in the present Specification (Para. [0018]) and claims. The present Specification discloses peptides of an average weight of 850 Daltons. Para. [0020]. In contrast, the '138 reference describes much larger peptides, the majority of which have a molecular weight of 25,000 to 67,000 Daltons. *See* ('138) Fig. 1. Even if the peptides of the present claims were contained within the composition with the larger peptides of the '138 preparation, there is no way to know that from reading the patent. There is also no suggestion in the patent that there is a low molecular weight fraction that could be isolated, or that any fraction of this preparation would have the cell growth activity of the claimed compositions.

D. The '138 reference teaches away from the present claims.

The '138 reference does not suggest that any useful fraction of peptides can be precipitated from a soluble preparation (*i.e.,* isolated from the filtrate) of oxidized hair. The '138 does teach that a fraction can be precipitated by lowering the pH of the solution to below 4:

> As previously stated, the present invention relates also to the process for recovering the solubilized product of the animal hairs which comprises admixing the solution of said product with an organic acid or an aqueous solution thereof to precipitate said product.
>
> * * *
>
> Under normal conditions, the pH of the mixed system of the solution of the solubilized product of the animal hairs and the organic acid may be adjusted less than about 4.5, preferably 1-4. **If the pH of the mixed system is more than 4.5, the solubilized product of the animal hairs becomes hard to precipitate.**

('138) Col. 4, lines 29-33, 58-63 (emphasis added). Thus, the '138 reference also teaches away from the present claims by teaching that the composition cannot be precipitated at pH above 4.5, and yet the claimed peptides are precipitated at neutral pH. Para. [0009]. Thus the claims are clearly distinguished from the disclosure of '138, both in the process of obtaining them and in their molecular weight, not just because of the process step alone, but because the different chemical characteristics of the two peptide compositions cause them to precipitate under different conditions.

Although the '138 patent discusses the use of a polar solvent such as alcohols, acetone and the like, this step is used to further purify the high molecular weight proteins that was the result of a previous acid precipitation and to "remove trace amounts of stinking components of low molecular weight, colored substances and the like contained in the solubilized product solution of the animal hairs," (Col. 5, line 24) and not to isolate a bioactive subfraction of peptides. The '138 can thus in no way be said to teach or suggest the present claims, and teaches away from the present claims by teaching precipitation from aqueous solution at low pH, and by teaching that only trace amounts of useless contaminants can be removed from the high molecular weight protein preparation by washing with aqueous solution of organic acids and/or volatile organic solvents. Therefore, the low molecular weight peptides does not meet the description the '138 disclosure. According to MPEP 2143.01, if, as in the present case, a modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Appellants submit therefore, that all rejections over '138 are improper.

In light of the lack of a *prima facie* case of obviousness by the Examiner, and further in light of the surprising results of the present disclosure, Appellants' claims are not obvious. The Board is respectfully requested to overturn the rejections under §103.

VIII. Conclusion

Appellant submits that all the Examiner's rejections and objections are overcome in light of the preceding arguments and evidence and Appellants request that all

rejections be overturned and the pending claims allowed without further amendment or prosecution.

IX. CLAIMS APPENDIX

1 – 54. (canceled)

55. (previously presented) A composition comprising water soluble peptides, wherein said peptides are obtained by:

oxidizing human or animal hair, human or animal nails, fur, hooves, or feathers, in an aqueous oxidizing solution;

filtering said aqueous oxidizing solution to obtain a water soluble portion;

substantially neutralizing said water soluble portion; and

adding a water-miscible organic solvent to said water soluble portion, such that a precipitate is formed;

wherein said precipitate comprises water soluble peptides;

and further wherein at least about 90% of said water soluble peptides are between about 300 and about 1300 daltons in molecular weight.

56. (previously presented) The composition of claim 55, further comprising the step of drying said precipitate to obtain a powder.

57. (previously presented) The composition of claim 55, wherein said oxidizing includes placing said hair, hooves, feathers, or human or animal nails in a solution comprising an oxidizing agent selected from hydrogen peroxide, peracetic acid, a percarbonate, a persulfate, chlorine dioxide, sodium peroxide, calcium peroxide, a perborate, or hypochlorite.

58. (previously presented) The composition of claim 55, wherein said oxidizing includes suspending said hair or feathers in a solution comprising from about 1 to about 32 volume percent peracetic acid or hydrogen peroxide.

59. (previously presented) The composition of claim 55, wherein said water-miscible organic solvent is methanol, ethanol, acetone, tetrahydrofuran or a combination thereof.

60. (previously presented) The composition of claim 55, wherein said water-miscible organic solvent is methanol.

61. (previously presented) The composition of claim 55, wherein said water-miscible organic solvent is ethanol.

62. (previously presented) The composition of claim 55, wherein said water soluble portion is concentrated up to about 10 fold prior to adding said water-miscible organic solvent.

63. (previously presented) The composition of claim 55, wherein said water-miscible organic solvent is added at a volume ratio of organic solvent to aqueous solution of from about 60:1 to about 100:1.

64. (previously presented) The composition of claim 62, wherein said water-miscible organic solvent is added at a volume ratio of organic solvent to aqueous solution of from about 6:1 to about 10:1.

65. (previously presented) The composition of claim 55, wherein the process comprises oxidizing human hair in an aqueous oxidizing solution.

66. (canceled)

67. (previously presented) The composition of claim 55, wherein said water soluble peptides have a mean molecular weight of about 850 daltons.

68. (previously presented) The composition of claim 55, wherein said water soluble peptides comprise from about 3.8 to about 4.78 weight percent sulfur.

69. (withdrawn) The composition of claim 55 wherein said precipitate is contained in a gel, lotion, paste, cream, or aqueous solution.

70. (withdrawn) The composition of claim 55, wherein said precipitate is a component of a wound dressing.

71. (withdrawn) The composition of claim 70, wherein said wound dressing is a sheet comprising a keratin derived product.

72. (withdrawn) The composition of claim 70, wherein said wound dressing is an adhesive bandage.

73. (withdrawn) The composition of claim 55, wherein said precipitate is a component of a tissue engineering scaffold.

74. (withdrawn) The composition of claim 73, wherein said tissue engineering scaffold comprises an insoluble keratin derived product.

75. (withdrawn) The composition of claim 55, wherein said precipitate is contained in or associated with a hydrogel.

76. (withdrawn) The composition of claim 75, wherein said hydrogel comprises a keratin derived hydrogel.

77. (withdrawn) A composition for topical application to skin of a human or animal subject, said composition comprising the soluble peptides of claim 55, contained in a lotion, gel, paste, cream, or aqueous solution.

78. (withdrawn) The composition of claim 77, wherein said water soluble peptides are obtained from human hair.

79. (withdrawn) The composition of claim 78, wherein said human hair is the hair of said human subject.

80. (withdrawn) The composition of claim 77, wherein said skin is damaged skin.

81. (withdrawn) The composition of claim 80, wherein said damaged skin includes a wound, a rash, diaper rash, a burn, a sunburn, a cut, an abrasion, a puncture, a sore, a bedsore, an ulcer, or wrinkled skin.

82. (withdrawn) A method of treating damaged epithelial tissue of a human or animal subject comprising contacting said damaged epithelial tissue with the composition of claim 77.

83. (withdrawn) The method of claim 82, wherein said damaged epithelial tissue includes a wound, a rash, diaper rash, a burn, a sunburn, a cut, an abrasion, a puncture, a sore, a bedsore, an ulcer, or wrinkled skin.

84. (withdrawn) The method of claim 82, wherein said water soluble peptides are obtained from human hair.

85. (withdrawn) The method of claim 84, wherein said human hair is the hair of said human subject.

86. (withdrawn) A wound dressing comprising the composition of claim 55 contained in, or adhered to a sheet, film or fabric dressing.

87. (withdrawn) The wound dressing of claim 86, wherein said sheet, film or fabric comprises a keratin derivative.

88. (withdrawn) The wound dressing of claim 86, wherein said wound dressing is an adhesive bandage.

89. (withdrawn) A cell growth scaffold comprising a keratin derived sheet material, porous material or hydrogel, and further comprising a composition of claim 55 contained in, or adhered thereto.

90. (withdrawn) A composition for the promotion of healing of damaged epithelial tissue comprising the composition of claim 55 contained in a hydrogel.

91. (withdrawn) The composition of claim 90, wherein said hydrogel is a keratin hydrogel.

92. (withdrawn) The composition of claim 90, wherein said epithelial tissue is skin, nasal, oral, gastro-intestinal, anal, vaginal, ear, eye, lung, or urogenital epithelial tissue.

93. (previously presented) A composition for topical application to skin of a human or animal subject, wherein said composition comprises the powder of claim 56.

94. (withdrawn) The composition of claim 93, wherein said powder is mixed with an absorbent material.

95. (withdrawn) The composition of claim 93, wherein said powder is mixed with a non-absorbent material.

96. (withdrawn) The composition of claim 95, wherein said non-absorbent material is a water insoluble keratin powder.

X. EVIDENCE APPENDIX

Appellant submit no evidence pursuant to 37 C.F.R. § 41.37(ix).

XI. RELATED PROCEEDINGS APPENDIX

No decisions have been rendered by a court or the Board in the Appeal filed in related U.S. Application Ser. No. 09/899,372.

Respectfully submitted,

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Date: December 7, 2007